Minute Order Form (rev. 12/90)

UNITED STATES DISTRICT COURT, NORTHERN DISTRICT OF ILLINOIS

Name of Assigned Judge or Magistrate Judge	*ROBERT W. GETTLEMAN*	Sitting Judge if Other Than Assigned Judge	
Case Number	*00 C ~~4791~~* 5791	Date	February 22, 2001
Case Title	Glaxo Group v Apotex, Inc.		

MOTION: [In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd-party plaintiff, and (b) state briefly the nature of the motion being presented.]

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "MOTION" box above]

(2) ☐ Brief in support of motion due _____

(3) ☐ Answer brief to motion due _____ Reply to answer brief due _____

(4) ☐ Ruling/Hearing on _____ set for _____ at _____

(5) ☐ Status hearing ☐ held ☐ continued to ☐ set for ☐ re-set for _____ at _____

(6) ☐ Pretrial conf. ☐ held ☐ continued to ☐ set for ☐ re-set for _____ at _____

(7) ☐ Trial ☐ Set for ☐ re-set for _____ at _____

(8) ☐ Bench Trial ☐ Jury Trial ☐ Hearing held and continued to _____ at _____

(9) ☐ This case is dismissed ☐ without ☐ with prejudice and without costs ☐ by agreement ☐ pursuant to ☐ FRCP 4(j) (failure to serve) ☐ General Rule 21 (want of prosecution) ☐ FRCP 41(a)(1) ☐ FRCP 41(a)(2)

(10) ☑ [Other docket entry]

Memorandum opinion and order entered.
Accordingly, defendant's motion to dismiss is denied.

(11) ☑ [For further detail see ☐ order on the reverse of ☑ order attached to the original minute order form.]

☐	No notices required, advised in open court.		number of notices
☐	No notices required.		
☑	Notices mailed by judge's staff.	FEB 23 2001	date docketed
☐	Notified counsel by telephone.		
☐	Docketing to mail notices.	C.S.	docketing dpty. initials
☐	Mail AO 450 form.		
☐	Copy to judge/magistrate Judge.		date mailed notice
GL	courtroom deputy's Initials	Date/time received in central Clerk's Office	mailing dpty. initials

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Document # 16

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

GLAXO GROUP LTD. and GLAXO WELLCOME, INC.,	)	
Plaintiffs,	)	No. 00 C 5791
v.	)	Judge Robert W. Gettleman
APOTEX, INC.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Glaxo Group Ltd. and Glaxo Wellcome Inc. ("plaintiff") have brought a two count anticipatory patent infringement complaint against defendant Apotex, Inc. In Count I, plaintiff requests a declaratory judgment, seeking to enjoin a future patent infringement. Count II alleges patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Defendant has moved to dismiss both counts, arguing that the court lacks jurisdiction over the first, and that the second fails to state a claim. For the reasons set forth below, the motion is denied.

Facts

Plaintiff is the owner of U.S. Patent No. 4,562,181 (the "181 patent") entitled "Amorphous Form of Cefuroxime Ester," which covers amorphous cefuroxime axetil. Plaintiff is also the holder of a new drug application ("NDA") for the antibiotic sulfur cefuroxime axetil tablets, which is covered by the 181 patent and is sold by plaintiff under the brand name Ceftin. Ceftin is a broad spectrum medicine used to combat graham positive and graham negative bacterial infections, and is the most often prescribed, largest selling branded cephalosporin

pharmaceutical in this country. The 181 patent was awarded on December 3, 1985, but filed on July 28, 1983. Pursuant to 35 U.S.C. § 154(c)(1), the patent expires on July 28, 2003, twenty years from the earliest United States filing date.[1]

Defendant is a Canadian company that engages in the manufacture of generic versions of prescription drugs which it markets throughout the world. On April 5, 2000, defendant filed an abbreviated new drug application ("ANDA") for permission to market a generic version of Ceftin, which was deemed acceptable for filing by the Food and Drug Administration ("FDA") on June 2, 2000.[2] Defendant's ANDA is currently under review by the Office of Generic Drugs at the FDA. The parties disagree on the length of the FDA's ANDA approval process. Defendant, relying on the affidavit of its Chairman and Chief Executive Officer, states that it expects the process to take no less than two years. According to plaintiff, the FDA has averaged 18 months for approvals. Under either scenario, the ANDA should be approved prior to expiration of the patent.[3]

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[1]The parties initially disputed the expiration date of the 181 patent. At oral argument the court directed the parties to file brief supplemental submissions on that issue. Defendant sent the court a letter explaining its position based on 35 U.S.C. §154(c)(1). Plaintiff sent a response letter, addressing other matters raised in plaintiff's letter, but not disputing plaintiff's calculation of the patent expiration date. The court considers this failure as an admission that the 181 patent expires on July 28, 2003.

[2]The parties agree that an ANDA is much simpler than an original NDA. An ANDA applicant is not required to demonstrate the drug's safety or effectivity; it relies on the NDA clinical trials. The ANDA applicant need show only that its proposed generic version is as "bioavailable" (the amount of active ingredient which reaches the blood stream) as the original drug.

[3]Generally, on a motion to dismiss for lack of jurisdiction, conflicts in the parties' affidavits should be resolved in the plaintiff's favor, which would favor the exercise of jurisdiction. See Millennium Products Inc. v. Gravity Boarding Co., Inc., ___ F. Supp. 2d ___, 2000 WL 1898580 (N.D. Ill. 2000).

By letter dated April 20, 2000, plaintiff gave defendant actual notice of the 181 patent (and others covering cefuroxime axetil). In that letter, plaintiff sought information as to whether defendant had filed an ANDA for cefuroxime axetil, if defendant planned to distribute or market generic cefuroxime axetil in the United States, and how the defendant's product and formulation differentiated from the claims of plaintiff's patents. Defendant has never provided such information despite repeated requests.

Finally, on July 28, 2000, plaintiff again wrote to defendant, specifically requesting information regarding: 1) whether defendant intends to market a cefuroxime axetil product in the United States and has applied to the FDA for approval of a generic form; 2) whether defendant believes that any generic product it will market would not infringe plaintiff's patents and why; and 3) whether defendant believes any of plaintiff's patents to be invalid. Receiving no response, plaintiff filed the instant lawsuit on September 20, 2000.

Discussion

In Count I, brought pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, plaintiff seeks a declaration adjudicating that defendant will infringe the 181 patent by its threatened acts of manufacture, importation and sale of products covered by the patent, and ordering that the effective date of any approval of defendant's ANDA for cefuroxime axetil tablets and their use be no earlier than the expiration date of the 181 patent. Defendant has moved to dismiss Count I pursuant to Fed. R. Civ. P. 12(b)(1), for lack of a justiciable controversy.

It is axiomatic that by enacting the Declaratory Judgment Act, "Congress enlarged the range of remedies available in the federal courts but did not extend their jurisdiction." Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671-72 (1950). The Act authorizes a court to

declare the rights of an interested party in a case of actual controversy within its jurisdiction. 28 U.S.C. § 2201. In the instant case, there is no question that jurisdiction over patent matters rests exclusively in the federal court. See 28 U.S.C. § 1338(a). Therefore, the sole requirement for jurisdiction under the Act is that there be an actual controversy, or a conflict that is "real and immediate" in that there is a "true actual controversy" between the parties. Lang v. Pacific Marine and Supply Co.Ltd., 895 F. 2d 761, 764 (Fed. Cir. 1990).

A patentee may seek a declaration that a person will infringe a patent in the future. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed Cir. 1997) (citing Lang, 895 F.2d at 763). When a patentee sues for a declaration of future infringement the actual controversy requirement "is met by a sufficient allegation of immediacy and reality." Lang, 895 F.2d at 764. To meet this actual controversy requirement, the patentee must demonstrate that: 1) the defendant is engaged in activity directed toward making, selling or using subject to an infringement charge, or be making meaningful preparation for such activity; and 2) the defendant's actions indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that suit will be forthcoming. Id. at 764. The first prong examines the accused infringer's conduct and ensures that the controversy is real and substantial. Id. The second prong requires conduct by both the accused infringer and the patentee, and ensures that the controversy is definite and concrete between the parties having adverse legal interests. Id.

In the instant case, the facts alleged in the complaint, and presented in the parties' moving papers pursuant to Fed. R. Civ. P. 12(b)(1), convince the court that both prongs have been met. First, defendant has filed and the FDA has accepted for filing the ANDA, which, as both parties

recognize, means that defendant is ready or has at least made meaningful preparations to be ready to market the allegedly infringing product. See Novopharm, 110 F.3d at 1570-71. Second, even accepting defendant's timetable, the ANDA is likely to be approved by June 2002, over a year before the patent expires. Obviously, the threat of defendant entering the market is not "years away," see Telectronics Pacing Systems, Inc. v. Ventritex, Inc., 982 F.2d 1520, 1527 (Fed. Cir. 1992), nor, in light of defendant's steadfast refusal to reply to plaintiff's demand letters, is there any real doubt that defendant plans to sell some form of cefuroxime axetil once the ANDA is approved.

Defendant argues that there is no evidence that it has decided whether and when to market the product. Defendant argues that it may decide to wait until plaintiff's patent expires. It is indisputable, however, that defendant has submitted the ANDA, "accompanied by data sufficient to make FDA approval eminent." Defendant's refusal to respond to plaintiff's letters inquiring about defendant's plans, coupled with defendant's same refusal at oral argument, along with the enormous amount of money at stake, leads to the inescapable conclusion that defendant plans to enter the market as soon as possible. Although it is true that there is no actual written threat of infringement as there was in Novopharm, 110 F.3d at 1571, defendant cannot defeat jurisdiction simply by refusing to put in writing what is otherwise obvious.

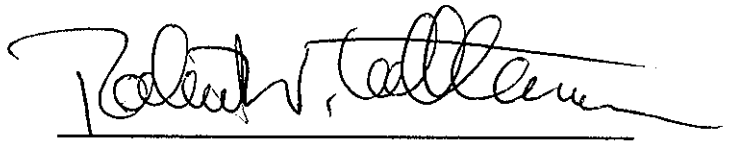
Based on these facts, the court concludes that the complaint alleges sufficiently that defendant is engaged in meaningful preparation of activity directed toward making, selling or using subject to an infringement charge, and that defendant has refused to change the course of its actions in the face of plaintiff's acts to preserve its patent rights. Accordingly, the court concludes that there is an actual controversy between the parties sufficient to support declaratory

judgment jurisdiction. To hold otherwise, as defendant requests, would be to close one's eyes to the economic realities of the situation. Plaintiff's cefuroxime axetil sales last year alone amounted to $610,000,000 world wide. Because an actual controversy exists, the court elects to exercise its discretion to take jurisdiction over the action.[4]

Conclusion

For the reasons set forth above, defendant's motion to dismiss is denied.

ENTER: February 22, 2001



Robert W. Gettleman
United States District Judge

[4]In Count II, plaintiff seeks to assert a claim under 35 U.S.C. § 271(a)(2)(A), which provides that it shall be an act of infringement to submit an application for an ANDA for a drug claimed in a patent if the purpose of such submission is to obtain approval to engage in the commercial manufacture or sale of the drug prior to the expiration of the patent. Defendant has persuasively argued that plaintiff cannot state a claim under § 271(a)(2)(A) because the section applies to "listed" drugs only, meaning drugs listed in the FDA Approved Drug Products with Therapeutic Equivalence Evaluation (the "Orange Book"). Because Ceftin, as an antibiotic, is not listed in the Orange Book, plaintiff persuasively argues that § 271(e)(2)(A) is inapplicable. See Abbott Laboratories v. Zenith Laboratories Inc., 934 F. Supp. 925 (N.D. Ill. 1995). As plaintiff correctly noted in oral argument, however, because plaintiff seeks the same relief under both counts, once this court has determined that it has and elects to exercise jurisdiction over Count I, it need not, at this time, reach the issue of whether Count II states a claim.